

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

BOTTLE OUTER CARTON TEXT

1. NAME OF THE MEDICINAL PRODUCT

Padovel 150 mg/37.5 mg/200 mg film-coated tablets

levodopa/carbidopa/entacapone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 150 mg of levodopa, 37.5 mg of carbidopa and 200 mg of entacapone.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet.

10 film-coated tablets

30 film-coated tablets

100 film-coated tablets

130 film-coated tablets

175 film-coated tablets

250 film-coated tablets

~~500 film-coated tablets~~

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

For 30 tablets' bottle pack:

After first opening 30 days.

For 175 tablets' bottle pack:

After first opening 175 days.

9. SPECIAL STORAGE CONDITIONS**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE****11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

SVUS Pharma a.s.
Smetanovo nábřeží 1238/20a,
500 02 Hradec Králové - Czech Republic
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fax: +420 495 214 192
e-mail: svus@svus.cz

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**

[To be completed nationally]